REMARKS

The specification has been amended to correct a typographical error. In the specification "0.015M sodium citrate" was erroneously written as "0.15M sodium citrate" and pyrrolidone was erroneously written as pyrolidone. The amendment corrects these inadvertent errors. Claims 1-4 and 22 were previously pending in this application. Claims 1, 3, 4, and 22 have been amended. Claim 1 has been amended to include the stringent hybridization conditions. Support can be found in the specification at least at page 11, lines 6-12. Claim 1 also has been amended to add the term "full-length" in section (c). Support for the amendment can be found throughout the specification in the recitation of full-length nucleic acid molecules. Claim 4 has been amended to remove the term "unique". Claim 4 has also been amended to include the phrase "between 8 and 2223 nucleotides in length" and the phrase "full-length". Support for these amendments can be found in the specification at least at page 13, lines 26-29, and throughout the specification in the recitation of full-length nucleic acid molecules, respectively. Claim 22 has been amended to eliminate non-elected subject matter and to remove the language relating to the control. No new matter has been added.

Claim Objections

The Examiner objected to claim 3 under 37 C.F.R. 1.75(c) as being in proper dependent form for failing to further limit the subject matter of a previous claim. Applicant respectfully traverses the objection.

The Examiner indicates in the Office Action at page 2 and again at page 5 that the polynucleotide sequence set forth as SEQ ID NO:15 is *larger* than the polynucleotide sequence set forth as SEQ ID NO:1, and the Examiner appears to base the objection to claim 3 on this erroneous assumption. Applicant respectfully submits that the polynucleotide sequence set forth as SEQ ID NO:15 in fact is a portion of SEQ ID NO:1. SEQ ID NO:1 has 2224 nucleotides and SEQ ID NO: 15 has 2172 nucleotides and is described on page 9, lines 18-20 as the "nucleotide sequence of the largest open reading frame of the human *vasa* cDNA of SEQ ID NO:1. Thus SEQ ID NO:15 is clearly a fragment of the longer *vasa* sequence set forth as SEQ ID NO:1. Applicant respectfully submits that claim 3 does further limit the subject matter of claim 1 in that the nucleotide sequence of SEQ ID NO:15 is a subset of the sequence set forth as SEQ ID NO:1.

Applicant respectfully requests the withdrawal of the objection to claim 3 under 37 C.F.R. 1.75(c).

The Examiner objected to claim 22 for recitation of an agent which selectively binds to an expression product of the nucleic acid of claim 1, which is a non-elected invention. Applicant has amended claim 22 to remove the recitation of the non-elected subject matter.

Rejection of Claims Under 35 U.S.C. §112, second paragraph

The Examiner rejected claims 4 and 22 under 35 U.S.C. §112, second paragraph as indefinite.

The Examiner indicates that the inclusion of the term "unique" as a limitation in claim 4 renders the claim indefinite. Applicant has amended claim 4 to remove the term "unique" and to further clarify the claim. The amended claim indicates that the isolated nucleic acid molecule is a fragment of SEQ ID NO:1 that is between 8 and 2223 nucleotides in length or is a full-length complement of a nucleic acid molecule with the above-described characteristics. Applicant respectfully submits that the amendments to the claim makes clear the metes and bounds of the claimed isolated nucleic acid molecules and obviates the basis of the indefiniteness rejection. Applicant respectfully requests that the rejection of claim 4 under 35 U.S.C. §112, second paragraph be withdrawn.

The Examiner rejected claim 22 under 35 U.S.C. §112, second paragraph as being unclear due to the inclusion of the phrase "measured value of binding". Applicant has amended claim 22 to remove language relating to the control from the claim. Applicant respectfully submits that this amendment obviates the rejection and requests reconsideration and withdrawal of the rejection of claim 22 under 35 U.S.C. §112, second paragraph.

Rejection of Claims Under 35 U.S.C. §112, first paragraph

The Examiner rejected claims 1, 4, and 22 under 35 U.S.C. §112, first paragraph as lacking adequate written description. As stated by the Examiner on page 4 of the Office Action, claim 1 is drawn to an isolated nucleic acid molecule selected from the group consisting of

nucleic acid which hybridize under stringent conditions to a molecule consisting of a nucleic sequence set forth as SEQ ID NO:1 which encodes a *vasa* polypeptide and degenerate coding sequences and complements thereof. The Examiner states that that the hybridization conditions set forth in the specification may or may not be high stringency conditions. Applicant has amended claim 1 to include the specific highly stringent hybridization conditions referred to in claim 1 as filed. Applicant respectfully submits that the inclusion of the specific highly stringent hybridization conditions obviates the Examiner's rejection. Applicant asserts that the use of hybridization methods are routine in the art and that one of ordinary skill in the art knows what wash temperature to use, particularly with all the other hybridization conditions being provided in the instant application.

Examiner also stated that "the claims are drawn to a genus of nucleic acids which is highly variant as said genus encompasses polynucleotides encoding polypeptides having numerous structural and functional attributes" (Office Action at Page 5), and infers that the disclosure fails to describe the common attributes or characteristics that identify the members of the genus. Applicant contends, on the contrary, that the specification does describe the common attributes of the claimed genus. First, the specification provides the sequence of SEQ ID NO:1 and SEQ ID NO:15. Second, the specification describes degenerate nucleotide sequences readily visualized by one of ordinary skill in the art. Third, the specification further describes the criteria for stringent hybridization conditions that circumscribe a set of nucleotide sequences having common structural features. Thus the specification provides a description of the structural features of the genus of nucleic acids (not to mention the functional features of the nucleic acids which also are described) that reasonably conveys to one of ordinary skill in the art that Applicant was in possession of the claimed invention. Thus the specification meets the standard set forth in the case law for written description of a nucleic acid.

The Examiner stated that "SEQ ID NO:1 does not sufficiently describe the claimed genus because of the structural and function al variation permitted within the genus" and thus contends that one of ordinary skill in the art would "reasonably conclude" that the specification does not provide a representative number of species to describe the genus. (Office Action at page 5). Respectfully, that statement does not set forth the correct standard. First, providing a representative number of species is but one of the ways in which a genus can be described. The

Lilly case does not suggest that it is the only way. *Regents of the University of California v. Eli Lilly and Co.* 43 USPQ 2d 1398 (Fed. Cir. 1997). Second, Applicant has described a number of species in the specification that the Examiner apparently has not considered. Applicant provided a number of other species by way of the description of hybridization conditions and the use thereof, as well as degenerate nucleotide sequences and conservative substitutions. In addition, Applicant submits that the specification describes SEQ ID NO:15, which is also a member of the claimed genus. As described above, Applicant submits that the Examiner misinterpreted the relationship between SEQ ID NOs:1 and 15. The Examiner erroneously concludes that the specification "also describes SEQ ID NO:15 as comprising 13 additional nucleotides on the 5' end and 38 nucleotides on the 3' end of SEQ ID NO:1" (Office Action at page 5). Applicant submits that as indicted in the specification at page 13, lines 30-31, SEQ ID NO:15 is a 2171 nucleotide-long portion of SEQ ID NO:1, which is 2224 nucleotides in length. In addition, the specification at page 9, lines 18 and 19, describes SEQ ID NO:15 as "the nucleotide sequence of the largest open reading frame of the human *vasa* cDNA of SEQ ID NO:1," which Applicant asserts clearly indicates to one of ordinary skill in the art that the nucleic acid set forth as SEQ ID NO:15 is a member of the claimed genus of claim 1.

The Examiner must keep in mind that the specification is written for one of ordinary skill in the art. Therefore, the proper inquiry is whether the specification has described a number of species through the various descriptions of nucleic acid species in the specification so that Applicant's possession of the claimed invention was reasonably conveyed to the person of skill in the art. Applicant contends that one of ordinary skill in the art would readily recognize that Applicant had possession of the invention based on the various described species of nucleic acids, just as if the specification set forth a large number of these molecules by mechanical substitution of individual nucleotides in SEQ ID NO:1.

Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 1 and claim 22, which depends from claim 1, under 35 U.S.C. §112, first paragraph.

The Examiner also rejected claim 4 under 35 U.S.C. §112, first paragraph but the basis of this rejection of claim 4 is unclear. The Examiner appears to characterize claim 4 as "drawn to polynucleotide sequences which hybridize under stringent conditions to SEQ ID NO:1 and

complements of SEQ ID NO:1" (Office Action at page 4). Applicant contends that although this characterization is correct with reference to claim 1, the same characterization does not apply to claim 4. Claim 4 as amended is drawn to nucleic acid fragments of SEQ ID NO:1 that are between 8 and 2223 nucleotides in length, excluding sequences having the database accession numbers of Table I, or sequences encoding a polypeptide having an amino acid sequence selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, and SEQ ID NO:7, and full-length complements and/or fragments thereof. Applicant respectfully submits that more than adequate written description has been provided for one of ordinary skill in the art to conclude that the Applicant was in possession of the claimed invention at the time of filing.

Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of claim 4 under 35 U.S.C. §112, first paragraph.

Rejection of Claims Under 35 U.S.C. §102(b)

The Examiner rejected claims 1 and 3 under 35 U.S.C. §102(b) as being anticipated by the New England Biolabs Catalog (1994, page 91).

Applicant has amended claim 1 to indicate that the complement in section (c), is a full-length complement. Applicant believes that this amendment obviates the rejection of claims 1 and 3 as anticipated by New England Biolabs Catalog (1994, page 91) as the random primers would not be full-length complements.

The Examiner rejected claim 4 under 35 U.S.C. §102(b) as being anticipated by Hloch et al (Nucleic Acids Research, 1990, Vol. 18, page 3045) as evidenced by Lemaire et al., (Life Sciences, 1993, vol.. 52, pp. 917-926), and Castrillon et al. (PNAS, 2000, Vol. 97 pp. 9585-9590). Applicant respectfully traverses the rejection and maintains Hloch et al does not anticipate the claimed invention.

The Examiner asserts that due to the fact that both p68 and the *vasa* polypeptides have conserved protein segments, a nucleotide fragment of claim 4 would be anticipated by the full sequence of p68 disclosed in the Hloch et al reference. Applicant respectfully submits that even if there is polypeptide similarity between regions of p68 and *vasa* protein, it does not mean that

the nucleotide sequence of p68 disclosed in the reference is identical to the sequences of nucleic acid fragments of claim 4. In fact, a Blast comparison between the cDNA sequence set forth in the cited Hloch et al reference and SEQ ID NO:1, indicate no regions of significant similarity even with the search word size set to the minimum size of 7 (see enclosed copy of Blast 2 Sequence results). The results of the Blast comparison between the two sequences indicates that there is no significant similarity found between the Hloch cDNA sequence and SEQ ID NO:1. Thus, Applicant respectfully asserts that the human p68 cDNA disclosed by Hloch et al does not comprise a fragment of SEQ ID NO:1 and the Hloch et al reference does not anticipate the claimed invention.

Applicant respectfully asserts that claim 4 is not anticipated by Hloch et al (Nucleic Acids Research, 1990, Vol. 18, page 3045) as evidenced by Lemaire et al., (Life Sciences, 1993, vol. 52, pp. 917-926), and Castrillon et al. (PNAS, 2000, Vol. 97 pp. 9585-9590), because Hloch et al does not teach every element of the claimed invention. Applicant respectfully requests withdrawal of the rejection of claim 4 under 35 U.S.C. §102(b).

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment that the application is not in condition for allowance, the Examiner is requested to contact the Applicant's representative at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

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